

REMARKS/ARGUMENTS

In response to the Non-Final Rejection mailed July 15, 2003, Applicants have amended Claims 5, 7 and 9 and present the following remarks.

Claims 5 and 6 were rejected under 35 USC 102(b) as being anticipated by Mirkov et al. Mirkov et al is cited for stating that STMV is a possible vector for making transgenic plants expressing bovine lysozyme. This rejection is respectfully traversed.

Mirkov et al does not disclose producing biologically active lysozyme in plants. All biologically active lysozyme protein shown as produced in Mirkov et al was produced in yeast. When Mirkov et al attempted to put the lysozyme gene in plants; they never showed that lysozyme protein was actually made. A portion of the protein may have been made as suggested by the immunoassay data but not biologically active protein. Likewise resistance in recombinant plants to infection suggests something is happening but was never shown to be due to lysozyme (or any other protein) produced by the plants. The net result is an allegation but NO proof that the plant cell itself can produce biologically active lysozyme.

Curiously, Mirkov et al did not report the results of a simple lysozyme biological assay with a plant produced product or extract. Mirkov et al did show that recombinant yeast produced biologically active lysozyme and that this yeast-produced product was protective on plants. However, neither assay suggests that the plant itself can produce lysozyme.

As a separate issue, STMV is satellite tobacco mosaic virus, which is a helper virus. By itself, the virus cannot reproduce in a plant or spread systemically. Claim 5 has been amended to require the claimed virus to perform such functions.

Furthermore, for reasons given in the previous response filed October 16, 2003, STMV is such a small virus that it is unlikely to be able to hold a bovine lysozyme gene and have a normal lifecycle. Furthermore, STMV requires a primary virus for a full infection. In order for Mirkov et al to perform the desired function of the presently claimed invention, additional components not taught by Mirkov et al will be required.

Therefore, the Mirkov et al disclosure is not enabling to teach anything which actually works and certainly not in the manner claimed.

Claims 5-10 were rejected under 35 USC 103(a) as being obvious over Mirkov et al taken in view of Donson et al. The rejection contends that Mirkov et al teaches a recombinant RNA plant virus having the bovine lysozyme gene. Donson et al is cited to teach recombinant tobamoviruses with subgenomic promoters controlling expression of a protein. The examiner contends that it would have been obvious to use the bovine lysozyme gene of Mirkov et al in a Donson et al vector system to express bovine lysozyme protein in plants. This rejection is respectfully traversed.

The examiner has argued that bovine lysozyme has been previously produced and that the previous arguments for unpredictability are accordingly not persuasive. However, the current claims require more than simple expression in a plant cell. The present claims recite that the virus containing the lysozyme gene be infectious and spread systemically, properties not needed in a traditional transgenic plant such as those actually prepared by Mirkov et al.

While the examiner had argued that the arguments were not commensurate in scope with the claims, such a statement cannot be maintained. All seven of the unpredictable points raised in the previous response filed October 16, 2003 are directly or indirectly implied by the present claims. To summarize:

- 1) The recombinant virus with the lysozyme gene must be able to replicate in the plant cell and infect other plant cells.
- 2) The recombinant virus must stably retain the lysozyme sequence to make the protein product in both the initial cells being infected and other cells infected during the process of systemic infection.
- 3) The specific recombinant construct must be compatible with the host plant cell.
- 4) To infect a whole plant the recombinant virus must be able to move throughout the growing parts of the plant while retaining the lysozyme gene.
- 5) The viral capsids must be able to assemble to encompass both the viral genome and an additional lysozyme gene.

- 6) The lysozyme gene must be expressed and not degraded by the plant cell.
- 7) The expressed lysozyme protein must be retained by the plant sufficiently to be detected in or recovered from the whole plant.
- 8) Unlike vectors containing a lysozyme gene, infectious viruses must retain all of the other biological properties in order to infect a whole plant.

Transgenic plants produced by the Mirkov et al methods require at most point 6 and 3 (using a different construct). Vectors making transgenic plants do not require the other features. Therefore, from Mirkov et al, one cannot automatically assume the other unpredictable features are practical. Dodson et al provides some assistance but not all proteins are expressible using Dodson et al's vector systems (assignee's previous work).

The rejection is based on an assumed a fact, which is not necessarily true. In the final rejection mailed June 28, 2004, page 4, lines 3-5 states: "Donson teaches the value of using a recombinant virus comprising viral subgenomic promoters to express proteins to confer bacterial resistance to plants." (The undersigned believes the examiner intends "...bacterial resistance in plants.") The bacterial resistance in Donson et al is produced by different proteins. The rejection appears based on the assumption that conferring bacterial resistance in Donson et al somehow suggests one is enabled to do likewise using lysozyme as the gene being carried by the vector. This assumption is false because a mere suggestion does not automatically enable.

Donson et al does NOT provide any suggestion that lysozyme can be produced at all. Particularly with the assignee's previous GENEWARE vectors, such as those taught by Donson et al, certain proteins cannot be made. For various reasons (some unknown due to the complexity of the system) such vectors will be fully functional for some genes and not for others. With the underlying assumption of the rejection being rebutted, it should be readily apparent that the rejection should be withdrawn.

Again as argued above, Mirkov et al never shows producing a biologically active bovine lysozyme protein in a plant. Therefore, one has even more reason to doubt that such can be done by the different viral vectors of the present invention. Accordingly, the

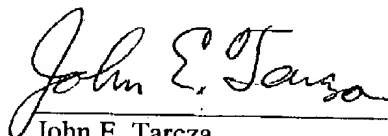
claims as written are not obvious over Mirkov et al in view of Donson et al and the rejection should be withdrawn.

In view of the above amendments and comments, the claims are now in conditions for allowance and applicants request a timely Notice of Allowance be issued in this application.

The commissioner hereby is authorized to charge payment of any fees under 37 CFR § 1.17, which may become due in connection with the instant application or credit any overpayment to Deposit Account No. 500933.

Respectfully submitted,

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John E. Tarcza
Reg. No. 33,638

John E. Tarcza
Intellectual Property Advisor
Large Scale Biology Corporation
3333 Vaca Valley Parkway, Suite 1000
Vacaville, CA 95688
301-371-7740 tel.
301-371-7745 Fax.
E-MAIL john.tarcza@lsbc.com